K110925

NOVABONE
DRIVING INNOVATION IN OSTEOBIOLOGICS

JUL - 5 2011

510(k) Summary 03/31/11
NovaBone MacroPor-Si$^+$ – Bioactive Bone Graft

1. Submitter Information:

Name:	NovaBone Products, LLC
Address:	13631 Progress Boulevard, Suite 600 Alachua, FL 32615
Telephone:	(386) 462-7661
Facsimile:	(386) 418-1636
Contact:	David M. Gaisser

2. Name of Device:

Trade Name:	NovaBone MacroPor-Si$^+$ – Bioactive Synthetic Bone Graft
Common Name:	Osteoconductive Bone Void Filler Synthetic Resorbable Bone Graft Material
Regulation Number:	21 CFR 888.3045
Regulation Name:	Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class:	Class II
Product Code:	MQV

3. Legally Marketed Predicate Device:

Predicate #1:	NovaBone Putty – Bioactive Synthetic Graft [K060728, K080009, K082672, K101860]
Predicate #2:	NovaBone Porous – Bone Graft Scaffold [K060432, K090731]

4. Device Description

NovaBone MacroPor-Si$^+$ is an osteoconductive, bioactive, bone void filler device. It is composed of a calcium-phosphorus-sodium-silicate (Bioglass) particulate mixed with a synthetic binder that acts as a temporary binding agent for the particulate. The particulate and binder are provided premixed as a pliable cohesive material. The mixed device is supplied sterile, packaged in a PET-G tray and outer peel pouch. On implantation, the binder is absorbed to permit tissue infiltration between the Bioglass particles. The particles then are slowly absorbed and replaced by new bone tissue during the healing process.

5. Intended Use

NovaBone MacroPor-Si$^+$– Bioactive Bone Graft is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone MacroPor-Si$^+$ is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

NovaBone MacroPor-Si$^+$ is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

6. Technological Characteristics and Substantial Equivalence

The technological characteristics of the new NovaBone MacroPor-Si$^+$ device are similar to the predicate devices. The new device and the predicates are designed as osteoconductive space-filling devices to be gently packed into defect sites and used as non-structural scaffolds for the body's natural healing and bone regeneration process. The indications for the new device are similar to those of the predicate devices. The device is intended to be used alone.

The primary component of NovaBone MacroPor-Si$^+$ is bioactive glass (45S5 Bioglass) particulate. This synthetic material is both biocompatible and osteoconductive. The NovaBone MacroPor-Si$^+$ also includes a synthetic binder as an inert carrier for ease of device handling and delivery, forming a premixed cohesive material. The binder is biocompatible and is absorbed after implantation, opening space between the bioactive glass particles for cell infiltration and bone formation. The bioactive glass particulate remains for a longer post-implantation period, acting as a scaffold for bone ingrowth. This particulate is absorbed and replaced by new bone tissue. Animal testing has demonstrated that the majority of the material is absorbed within six months of implantation, with >98% of the material being absorbed by 12 months. The timeframe for full absorption in humans has not been determined, but is expected to be at least 12 months.

The NovaBone MacroPor-Si$^+$ device of this submission is a modification to the predicate NovaBone Putty device. A portion of the particulate bioactive glass component of the NovaBone Putty device has been replaced with a chemically-identical bioactive glass component, but having a porous structure. The porous component of the modified Putty device is identical to the NovaBone Porous predicate. The device is designed to be gently packed into osseous defect sites and used as a non-structural scaffold for the body's natural healing and bone regeneration process. The device acts as a synthetic, inorganic, biocompatible and osteoconductive scaffold into which new bone will grow.

7. Conclusion

The NovaBone MacroPor-Si$^+$ device is a modification of the predicate NovaBone Putty and NovaBone Porous devices, replacing a portion of the amorphous bioactive glass particulate content of the NovaBone Putty device with the porous bioactive glass particulate of the NovaBone Porous predicate to provide a device with increased porosity for tissue ingrowth. This device modification does not result in a change in technological characteristics of the device. NovaBone MacroPor-Si$^+$ is a safe and effective device for use as a non-structural osteoconductive bone void filler for osseous defects. *In vivo* performance data are presented in support of the new device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NovaBone Products, LLC
% Mr. David M. Gaisser
13631 Progress Boulevard, Suite 600
Alachua, Florida 32615

JUL - 5 2011

Re: K110925
Trade/Device Name: NovaBone MacroPor-Si^{+} - Bioactive Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: May 24, 2011
Received: May 25, 2011

Dear Mr. Gaisser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): **K110925**

Device Name: NovaBone MacroPor-Si$^+$ – Bioactive Bone Graft

Indications For Use:

NovaBone MacroPor-Si$^+$– Bioactive Bone Graft is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone MacroPor-Si$^+$ is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

NovaBone MacroPor-Si$^+$ is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Prescription Use XX OR (Per 21 CFR 801.109) Over-The-Counter Use_____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110925